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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,119

01/17/2006

Cinderella Christina Gerhardt

F7718(V)

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201 7590 07/14/2008
UNILEVER PATENT GROUP
800 SYLVAN AVENUE
AG West S. Wing
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

PANDE, SUCHIRA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

07/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,119	Applicant(s) GERHARDT ET AL.	
	Examiner SUCHIRA PANDE	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-9,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5-9,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2008 has been entered. The claim set submitted on January 30, 2008 along with the arguments submitted on November 30, 2007 are being considered in this action.

Claim Status

2. Amendment filed on January 30, 2008 is acknowledged. Claims 1-2, 4, 10-11 are cancelled; claims 3, 8 and 12 have been amended; new claim 13 has been added. Currently claims 3, 5-9 and 12-13 are active and will be examined in this action.

Response to Arguments

Re 112 2nd rejection of claims 3, 5-9, 12

3. Amendment to base claim 3 does not overcome the 112 2nd rejections of claims 3, 5-8. Amendment to the claim 3, adds an intermediary step, however the claim in present form contains no active steps. To illustrate the point Examiner is giving an example. "----growing a cell ----- in ----medium" indicates an active step. The claim as recited states "---cell is grown---". "-----the cells are exposed to a test compound---". In the presently recited claims where passive voice is used there are no active steps in the claim. Accordingly 112 2nd rejections of claims 3, 5-9 and 12 are being maintained.

Amended claim 12 is drawn to a method according to claim 3 comprising screening the test compound for drugs or functional ingredients for food products that modulate feelings of satiety or appetite in humans or animals. The amended claim as recited does not overcome the 112 2nd rejection because the claim as recited is still lacking in recitation of active steps that must be followed to achieve the intended desired end result, namely, screening the test compound for drugs or functional ingredients for food products that modulate feelings of satiety or appetite in humans or animals. In other words the claimed method lacks the active step that should be performed in addition to claim 3 that will allow one to screen a test compound for drugs or functional ingredients for food products that modulate feelings of satiety or appetite in humans or animals.

Hence 112 2nd rejection of claim 12 is being maintained.

Claim interpretation

4. Regarding claim 12, in absence of active method steps the teaching from prior art that ghrelin is produced by stomach and acts on various parts of brain is being broadly interpreted to mean that changes in secretion of ghrelin will have an effect on brain which in turn will modulate feelings of satiety or appetite in humans or animals.

Re 103 (a) rejection of claims 3, 5-6 and 9 over Atten et al. in view of Ji et al. and further in view of Kojima et al.

5. Applicant's arguments filed November 30, 2007 have been fully considered but they are not persuasive. Applicant has amended base claim 3 and is arguing the motivation to combine references. Amended claim 3 is a method where test compounds

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are screened for their effect on ghrelin expression. The method requires use of cell lines identified by their ATCC numbers that should be grown in a suitable media. Cited art Atten et al teaches : wherein the cell line is selected from RF-1 having ATCC number CRL-1864 and RF-48 having ATCC number CRL-1863 (see page 1424 section 2.2 where RF-1 having ATCC number CRL-1864 and RF-48 having ATCC number CRL-1863 are taught). Atten et al. also teach the exact growth media claimed in the instant application to grow these cell lines. Atten et al. teach wherein the medium is Leibovitz's L15 containing 10% (vol/vol) foetal bovine serum and 2 mM L-glutamine, and wherein the cell line is grown at a temperature of 37.degree. C. in the absence of CO₂ (see page 1424 section 2.2.). Atten et al. states the Leibovitz's media taught is supplemented with non-essential amino acids and do not explicitly recite using 2 mM L-glutamine. Glutamine is classified as a nonessential amino acid (see report in Le Magazine published on September 1999 by Greenwell). One of ordinary skill in the art knows that MEM media routinely used for cell culture contains 292 mg/l L-glutamine. Using the formula weight provided by Sigma Aldrich as 146.14 for L-glutamine one can calculate that 292.28 mg of L-glutamine/l media would result in 2 mM L-glutamine. So its clear that one of ordinary skill would add the appropriate amount of L-glutamine as a non-essential amino acid to the media taught by Atten et al.

Since the claimed cell line and the growth media and conditons of growth claimed are identical to those taught by prior art. Then its inherent that the genes expressed by these identical cells under those identical growth conditions are inherently the same as those instantly claimed. In other words its inherent property of CRL-1864

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and CRL-1863 cell lines that they produce ghrelin when grown in above growth conditions. If these cells are exposed to a test compound then if it has an influence on the expression/synthesis of ghrelin (which is an inherent property of the claimed cell lines as explained above) that can be measured thereby one can screen for effects of test compounds on ghrelin expression and/or secretion. Cited art Ji et al. teaches use of cell lines RF-1 (having ATCC number CRL-1864) and RF-48 (having ATCC number CRL-1863) to screen a variety of compounds. In view of the combined teachings of Atten et al. and Ji et al. it would be obvious to one of ordinary skill to practice the method of screening compounds as taught by Ji et al. in the method of Atten et al. Thus cited art does teach the method of amended claim 3.

Hence previously cited 103 (a) rejection of claims 3, 5-6 and 9 are being maintained.

Re 103 (a) rejection of remaining claims 7-8 and 12 over Atten et al. ; Ji et al. and

Kojima et al. further in view of appropriate secondary references

6. Since rejection of base claim 3 over Atten et al. ; Ji et al. and Kojima et al. is being maintained, accordingly rejection of dependent claims 7-8 and 12 further in view of appropriate secondary references is also being maintained.

Claim Objections

7. Claim 3 is objected to because of the following informalities: Applicant has used parenthesis ---the (regulation of) expression--- in the claim. It is not clear what Applicant intends to convey by use of parenthesis. If the intent is to delete the phrase then

Applicant should use standard technique of lining through the phrase. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 3, 5-9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Regarding claim 3, the amended claim as recited is missing active method steps. Claims 5-9 and 12-13 depend from claim 3, hence share the same 112 2nd problem.

Amended claim 12 is drawn to a method according to claim 3 comprising screening the test compound for drugs or functional ingredients for food products that modulate feelings of satiety or appetite in humans or animals. The amended claim as recited is still lacking in recitation of active steps that must be followed to achieve the intended desired end result, namely, screening the test compound for drugs or functional ingredients for food products that modulate feelings of satiety or appetite in humans or animals. In other words the claimed method lacks the active step that should be performed in addition to claim 3 that will allow one to screen a test compound for drugs or functional ingredients for food products that modulate feelings of satiety or appetite in humans or animals. No guidance is provided to one of ordinary skill how to perform the method such that the desired end result namely screening a test compound for drugs or functional ingredients for food products that modulate feelings of

satiety or appetite in humans or animals can be achieved.

Hence claims 3, 5-9, 12 and 13 are all rejected under 112 2nd paragraph.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3, 5- 6, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atten et al. (2001) Biochemical Pharmacology 62: 1423-1432 in view of Ji et al. (2002) Oncogene 21:6549-6556 and further in view of Kojima et al (1999) Nature 402:pp 656-659.

Regarding claim 3, Atten et al. teach : wherein a cell line is selected from RF-1 having ATCC number CRL-1864 and RF-48 having ATCC number CRL-1863 (see page

1424 section 2.2 where RF-1 having ATCC number CRL-1864 and RF-48 having ATCC number CRL-1863 are taught).

Regarding claim 3, Atten et al. do not recite the use of cell line RF-1 and RF-48 in a method for assessing the (regulation of) expression, synthesis and/or secretion of ghrelin.

Regarding claim 3, Ji et al. teach use of the cell line RF-1 and RF-48 in a method where the (regulation of) expression, synthesis (see title and page 6556 where Ji et al. teach use of these cell lines submitted to ATCC as models) are monitored. Ji et al. teach comprehensive analysis of gene expression profiles in human gastric cancer cell lines (see abstract). On page 6552, par. 2 Ji et al. teaches gastric carcinoma cell lines (RF1 and RF48).

Regarding claim 3, neither Atten et al. nor Ji et al. explicitly state that RF-1 and RF-48 is a cell line capable of producing ghrelin.

Regarding claim 3, Kojima et al. teach ghrelin is a growth-hormone-releasing acylated peptide from stomach. (see Kojima et al. 1999 where identification of purified ghrelin ligand from stomach (gastric tissue) is taught). RF-1 as a cell line derived from gastric adenocarcinoma. Kojima et al teaches one of ordinary skill in the art that ghrelin is a growth-hormone-releasing acylated peptide from stomach. Since both the cell lines taught RF-1 and RF-48 are gastric cell lines hence they are capable of producing ghrelin is an inherent property of these two cell lines. It is obviously clear to one of ordinary skill in the art that cells have to be grown under appropriate conditions if one wants to examine expression of a specific marker. If one was interested in studying

expression of ghrelin from a cell line derived from a gastric adenocarcinoma and capable of producing ghrelin. The one would grow it in a suitable medium. The suitable growth medium and conditions required are taught by Atten et al. (see page 1424 section 2.2 where media and conditions required to grow RF-1 cells is described).

Moreover since Ji et al. teach gene expression profiling of several gastric cell lines including RF1 and RF48, it is inherent that the method taught by them is capable of assessing the (regulation of) expression, synthesis and/or secretion of ghrelin (which as indicated above is an inherent property of the two cell lines taught). In addition Ji et al. teach large -scale drug (test compounds) screening using cell lines (see page 6549 par. 3). By these combined teachings, Ji et al. teach a test compound when screened using the above cell lines will provide information about the effect of these compounds on ghrelin expression and /or secretion. Thus allowing for a method to screen the compounds for their effect on ghrelin expression and /or secretion.

Thus Atten et al. in view of Ji et al. and Kojima et al. teach a method for assessing the (regulation of) expression, synthesis and /or secretion of ghrelin, wherein a cell line selected from RF-1 having ATCC number CRL-1864 and RF-48 having ATCC number CRL-1863, capable of producing ghrelin when grown in a suitable medium is grown in such medium, and cells of said cell line are exposed to a test compound wherein the effect of said compound on ghrelin expression and /or secretion is screened.

Regarding claim 5, Atten et al. teach wherein the medium is Leibovitz's L15 containing 10% (vol/vol) foetal bovine serum and 2 mM L-glutamine, and wherein the

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cell line is grown at a temperature of 37⁰C in the absence of CO₂ (see page 1424 section 2.2.). Atten et al. states the Leibovitz's media taught is supplemented with non-essential amino acids and do not explicitly recite using 2 mM L-glutamine. Glutamine is classified as a non-essential amino acid (see report in Le Magazine published on September 1999 by Greenwell). One of ordinary skill in the art knows that MEM media routinely used for cell culture contains 292 mg/l L-glutamine. Using the formula weight provided by Sigma Aldrich as 146.14 for L-glutamine one can calculate that 292.28 mg of L-glutamine/l media would result in 2 mM L-glutamine. So it is clear that one of ordinary skill would add the appropriate amount of L-glutamine as a non- essential amino acid to the media taught by Atten et al. Thus all elements of claim 5 are taught by Atten et al.

Regarding claim 6, Atten et al. teach cell culture conditions for the two cell lines taught. They do not explicitly state that, wherein the medium is changed at least every 4 days. However this is a fact that is well known to one of ordinary skill in the art of mammalian tissue cell culture (see Basic Techniques for Mammalian cell tissue culture unit 1.1.2 where Mary C. Phelan describes in step 7. If necessary, feed subconfluent cultures after 3 or 4 days by removing old medium and adding fresh medium.)

Regarding claim 9, Atten et al. teach wherein the cell line is exposed to a variety of test compounds (see title and abstract where exposure to test compound Resveratrol (potential chemo preventive candidate against gastric cancer is taught, see page 1430 last par. last line.). Ji et al. teach that variety of test compounds is indeed routinely used

to study responsiveness of each cell line (see Ji et al. page 6551. par. 1). This teaching inherently requires that cell line under question be exposed to those test compounds).

Regarding claim 12, Atten et al. in view of Ji et al. and Kojima et al. teach method of claim 3. Further regarding claim 12, Kojima et al. state “ Taken together with the fact that ghrelin, when injected intravenously, induces GH (growth hormone) release, it is highly likely that this molecule (ghrelin) is produced in and secreted from the stomach, circulating in the blood stream to act on pituitary” (see page 659 par. 1). They further state “these results suggest that ghrelin in the arcuate nucleus may act on the hypothalamus or be transported to anterior pituitary’ (see page 659 par. 2). Finally they state :”Thus, the occurrence of ghrelin in both stomach and hypothalamus will give new dimension to the regulation of GH release. -----Ghrelin may thus have multifaceted roles in, for example the cardiovascular system and metabolism” (see page 659 par. 3). Thus Kojima et al. teach to one of ordinary skill in the art that ghrelin is produced by stomach into blood and its carried to brain where it acts on various parts of brain (arcuate nucleus/ hypothalamus/anterior pituitary) that are control feelings of satiety or appetite in humans or animals.

It would have been prima facie obvious to one of ordinary skill in the art to practice the method of Ji et al. and Kojima et al. in the method of Atten et al. at the time the invention was made. The motivation to do so is provided to one of ordinary skill by the art itself. Kojima et al. teaches to one of ordinary skill in the art that ghrelin is produced by stomach into blood and its carried to brain where it acts on various parts of brain (arcuate nucleus/ hypothalamus/anterior pituitary) that are control feelings of

satiety or appetite in humans or animals. Ji et al. teaches use of gastric cell lines RF-1 and RF-48 to screen a variety of compounds. If one was interested in screening for compounds that affect ghrelin production which in turn goes by blood to effect the appropriate part of brain to effect feelings of satiety or appetite in humans or animals, then the adenocarcinoma cell lines RF-1 and RF-48 would be obvious candidates in view of teachings of Kojima et al. since Atten et al. provide the detailed step by step protocol of the culture conditions and media required to grow these cell lines. Thus by using the combination of the above methods one of ordinary skill in the art would be able to screen for compounds that affect ghrelin production using these cell lines taught to them by prior art.

13. Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Atten et al. (2001) Biochemical Pharmacology 62: 1423-1432 in view of Ji et al. (2002) Oncogene 21:6549-6556 and further in view of Kojima et al (1999) Nature 402:pp 656-659 as applied to claim 3 above, and further in view of Chopin et al. (2002) WO 02/090387 A1 published 14 November 2002.

Regarding claim 7, Atten et al; Ji et al. and Kojima et al. teach method according to claim 3.

Regarding claim 7, Atten et al; Ji et al. and Kojima et al. do not explicitly spell out wherein the cell line is plated and grown in a culture plate after achieving cell confluence, wherein the plate is stored under the same incubation conditions as those used for growing the cell line (since Atten et. al. teaches media and cell culture conditions used for the cell lines claimed in the present invention it is obvious that above

conditions specified are inherently obvious to one of ordinary skill), and wherein ghrelin production is measured using an immunoassay kit.

Regarding claim 7, Chopin et al. teach wherein the cell line is plated and grown in a culture plate after achieving cell confluence (see page 25, lines 24-26 where culture of cells in 96 well plates for 3 days at 37⁰C is taught), wherein the plate is stored under the same incubation conditions as those used for growing the cell line (for the purposes of detecting ghrelin which is a small amino acid peptide it is obvious to one of ordinary skill in the art that the culture plate needs to be stored under conditions where the ghrelin peptide will not be destroyed. Culturing the cells in the media containing Liebovitz's media under the conditions specified in claims 1, 3 and 5 above results in production of ghrelin. Therefore it is inherently obvious to one of ordinary skill that storing the plates containing the produced ghrelin under the same incubation conditions as those used for growing the cell line will not destroy the ghrelin produced.

and wherein ghrelin production is measured using an immunoassay kit (Chopin et al. teach use of three different assays using antibodies raised against ghrelin (see page 24, line 23-25. Therefore by teaching Western blots, immunohistochemistry and ELISA assay for ghrelin using anti-ghrelin antibodies raised against whole human ghrelin peptide, Chopin et al. teach immunoassays that use anti-ghrelin antibodies. Thus Chopin et al. inherently teach all the components required to perform these immunoassays that would be packaged in a kit.

It would have been prima facie obvious to one of ordinary skill to practice the method of Chopin et al. in the method of Atten et al; Ji et al. and Kojima et al. to

measure the ghrelin peptide production by these cells at the time the invention was made. The motivation to do so is provided by Chopin et al. who teach availability of antibodies raised against ghrelin thus providing the reagent required by one of ordinary skill in the art to perform immunoassays to detect ghrelin.

14. Claims 7-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atten et al. (2001) Biochemical Pharmacology 62: 1423-1432 in view of Ji et al. (2002) Oncogene 21:6549-6556 and further in view of Kojima et al (1999) Nature 402:pp 656-659 as applied to claim 3 above, and further in view of Korbontis et al. (2000) The Journal of Clinical Endocrinology & Metabolism vol. 86: pp 881-887.

Regarding claim 8, Atten et al; Ji et al. and Kojima et al. teach method according to claim 3.

Regarding claim 8, Atten et al; Ji et al. and Kojima et al., do not explicitly teach wherein the cell line is used to study ghrelin gene expression.

Regarding claim 13, Atten et al; Ji et al. and Kojima et al., do not explicitly teach wherein the cell line is used to study ghrelin gene expression by means of quantitative RT-PCR.

Regarding claim 8, Korbontis et al. teach wherein the tumor cells are used to study ghrelin gene expression (see title and abstract), preferably by means of quantitative RT-PCR (see page 883 section Quantitative RT-PCR).

Regarding claim 13, Korbontis et al. teach wherein the tumor cells are used to study ghrelin gene expression (see title and abstract), preferably by means of quantitative RT-PCR (see page 883 section Quantitative RT-PCR).

Regarding claim 7, Korbontis et al. teach Ghrelin RIA that is capable of detecting both octanoylated (active) and non octanoylated (inactive) forms of ghrelin peptide. Thus by teaching the two separate polyclonal antibodies of ghrelin that are useful for detecting the above two forms of ghrelin peptide and their use in RIA, Korbontis et al. teach immunoassay that can be used monitor ghrelin production. By teaching the immunoassay, Korbontis et al. obviously teach all the components of the kit required to detect ghrelin using the immunoassay.

It would have been prima facie obvious to one of ordinary skill in the art to practice the method of Korbontis et al. in the method of Atten et al as evidenced by Ji et al. at the time the invention was made. The motivation to do so is provided to one of ordinary skill by the fact that Korbontis et al. use the Quantitative RT-PCR method to study expression of ghrelin and ghrelin RIA.

They used primary tumor tissues expressing ghrelin as their starting material. Atten et al. as evidenced by Ji et al. teach study of gene expression in gastric adenocarcinoma cell line using micro arrays. Atten et al; Ji et al. and Kojima et al. have shown (see supra) that two of the gastric adenocarcinoma cell lines (RF1 and RF48) produce ghrelin. Given the above fact pattern it is obvious to one of ordinary skill in the art that use of Quantitative RT-PCR method of Korbontis et al. will be able to detect ghrelin gene expression in the cell lines claimed. The advantages and ease of working with established cell lines (RF1 and RF48) available through ATCC (ATCC #CRL-1864 and ATCC # CRL-1863) vs. primary tumors tissue are well known to one of ordinary skill well versed in mammalian tissue culture.

Further use of method of Korbontis et al. allows one of ordinary skill to be able to monitor both the gene expression and actual production of ghrelin peptide. Thus enabling one to arrive at comprehensive picture of the various levels of controls (transcriptional and translational) that are operational under given experimental conditions.

Conclusion

15. All claims under consideration 3, 5-9, 12 and 13 are rejected over prior art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Suchira Pande
Examiner
Art Unit 1637

/Teresa E Strzelecka/

Primary Examiner, Art Unit 1637

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